



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0320]

Determination That PFIZERPEN (Penicillin G Potassium) Injection, 1 Million Units/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for penicillin G potassium injection, 1 million units/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure.

ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not

have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is the subject of ANDA 60-657, held by Pfizer, Inc., and initially approved on August 30, 1968. ANDA 60-657 is considered the designated reference standard. PFIZERPEN is indicated in the treatment of serious infections caused by susceptible strains of the designated microorganisms in certain conditions such as septicemia, pneumonia, meningitis, anthrax, and listeria.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is currently listed in the “Discontinued Drug Product List” section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated May 27, 2008 (Docket No. FDA-2008-P-0320), under 21 CFR 10.30, requesting that the Agency determine whether PFIZERPEN (penicillin G

potassium) Injection, 1 units/vial, and penicillin G potassium injection, 1 million units/vial, had been withdrawn from sale for reasons of safety or effectiveness. Penicillin G potassium Injection, 1 million units/vial, is the subject of ANDA 65-079, held by Sandoz, and approved on August 30, 2002.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness (this determination also applies to penicillin G potassium injection, 1 million units/vial, ANDA 65-079). The petitioner believes that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness because it was discontinued due to commercial reasons. We have carefully reviewed our files for records concerning the withdrawal of PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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